K01 2475

OCT 24 2001

510(k) Summary **CAAS II QVA**

This summary statement complies with 21CFR, section 807.92(c).
Date summary prepared: 30 July 2001

This premarket notification has been submitted by Pie Medical Imaging BV and covers the CAAS II QVA software package. Pie Medical Imaging is located at:

Pie Medical Imaging BV
Becanusstraat 13 D
6216 BX Maastricht
The Netherlands
tel +31.43.3281328
fax +31.42.3281329
e-mail: pmi@pie.nl

The contact person is: Ms. Carla de Vries, Quality Assurance assistant
The trade name is: CAAS II QVA
The common name for this type of device is:
Quantitative Vascular Analysis Software
and the classification name is
Image Processing System (LLZ).

The above as stated in 21 CFR, part 892.1570, has been classified as regulatory Class II.

The CAAS II QVA software package is substantially equivalent to the CAAS II QCA software package known under FDA number K945540.

The CAAS II QVA is one of the software modules intended to run on the Cardiovascular Angiography Analysis System mark II, CAAS II. It functions in the same manner as other vascular analysis software packages.
After the selection of the arterial segment of interest the contour of this arterial segment is automatically detected. Based on the contour information a number of analysis results can be calculated. Two methods for obstruction analysis are available, one with automatic reconstruction of the arterial wall to estimate the normal diameter or reference diameter for the obstruction, calculation of the MLD and % stenosis. The second method allows for manual selection of one or more reference position in the arterial segment and based on the MLD and this calculated reference for the position of the MLD the % stenosis is calculated.
In the arterial segment under study one or more subsegments can be selected by the user and for all these user defined subsegments the minimum, maximum and mean diameter are calculated.
Besides diameter information also cross sectional area is calculated over the arterial positions of interest. These cross sectional areas are calculated based on both circular symmetry of the artery and densitometric analysis of the contrast volume in the artery.
The QVA package can be used on arteries up to 50mm in diameter.

The intended use of the CAAS II QVA is:

1. Optimizing the quantitation of artery dimensions – to be used in clinical trials and in clinical cath lab environment
2. Managing of data resulting of the analysis of artery dimensions

The CAAS II QVA is equivalent in technological characteristics to the predicate device mentioned in this summary:

- The automatic contour detection of the CAAS II QVA software is similar to the contour detection algorithms used in the predicate devices.
- The CAAS II QVA software produces similar results as the predicate devices.

The CAAS II QVA is produced under the same Quality Assurance system applicable to the development and production of products currently marketed by Pie Medical Imaging.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 4 2001

Ms. Carla de Vries
Quality Assurance Assistant
Pie Medical Imaging BV
Becanusstraat 13 D
6216 BX Maastricht
The Netherlands

Re: K012475
Trade/Device Name: CAAS II QVA
Vascular analysis software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving
and Communications System
Regulatory Class: II
Product Code: 90 LLZ
Dated: July 30, 2001
Received: August 2, 2001

Dear Ms. deVries:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Notification - CAAS II QVA

INDICATION FOR USE STATEMENT

510(k) number (if known): K01 2475

Device Name: CAAS II QVA

Indications For Use:

1. Optimizing the quantitation of artery dimensions - to be used in clinical trials and in clinical cath lab environment
2. Managing of data resulting of the analysis of artery dimensions

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012475

(Optional Format 1-2-96)